# SAS-B Application

## Patient Information and Consent Form

**The Clinical Application of Medicinal MDMA for the Treatment of**

**Post-traumatic Stress Disorder**

**What is PTSD?**

Beyond Blue describes PTSD as “a particular set of reactions that can develop in people who have been through a traumatic event which threatened their life or safety, or that of others around them”.[[1]](#endnote-1) According to the Multidisciplinary Association for Psychedelic Studies (MAPS), PTSD is recognised as a complex biopsychosocial condition, often characterised by a number of symptoms including:[[2]](#endnote-2)

1. hypervigilance, anxiety, and sleep disturbance.
2. Intrusive memories, nightmares, or flashbacks.
3. Avoidance symptoms, including emotional numbing and withdrawal.

**What are the current treatment options?**

There are a variety of treatment options for PTSD. However, trauma focused psychotherapy has been shown to be the most effective. Trauma focused psychotherapy modalities include; Trauma-Focused Cognitive-Behavioural Therapy, Eye Movement Desensitization and Reprocessing, Exposure Therapy and Somatic Experiencing among others. While some patients experience clinical improvement in their PTSD symptoms from psychotherapy, many still retain the PTSD diagnosis, and may experience long-term debilitating symptoms[[3]](#endnote-3)[[4]](#endnote-4).

**What is medicinal MDMA-assisted therapy and why is it helpful?**

Medicinal MDMA-assisted therapy combines traditional trauma focused therapy approach with the ingestion of medicinal MDMA in a clinical setting. Medicinal MDMA is a compound that has anti-anxiety and prosocial effects which support a patient to connect with themselves and their treating therapist. It could be said medicinal MDMA acts as a catalyst for the therapeutic process.

What is the current research around MDMA-assisted therapy?

Over the past decade, MAPS completed six Phase 2 trials testing medicinal MDMA-assisted psychotherapy for the treatment of PTSD. 105 participants underwent a treatment program that included preparatory and follow-up psychotherapy sessions, along with two or three supervised medicinal MDMA or placebo sessions. The data across these trials showed that, overall, 54% of participants in the medicinal MDMA group no longer met diagnostic criteria for PTSD, compared with 23% in the placebo group. It was also found that patients treated with medicinal MDMA-assisted therapy continued to improve over subsequent follow-ups. These results are especially significant given the severe and previously resistant nature of the PTSD of most of the participants.

**How does medicinal MDMA exert its effects?**

Neurologically, patients with PTSD have been shown to experience increased blood flow in the amygdala, and disrupted activity in prefrontal regions. During the therapeutic session medicinal MDMA decreases blood flow to the amygdala and modulates the connectivity of medial prefrontal regions. This neurobiological state creates a receptive state for therapeutic work by decreasing the experience of fear and enhancing a patient’s capacity for communication, memory recall and self-compassion. By decreasing fear, and enhancing a patient’s capacity for communication, memory recall and self-compassion, this supports a receptive state of mind for therapeutic work[[5]](#endnote-5).

**What does MDMA-assisted psychotherapy look and feel like?**

Medicinal MDMA-assisted psychotherapy occurs within a safe, private space, that’s free from interruption and with minimal external stimuli. During the therapeutic process, two trained specialists will support you throughout the therapy. After consuming the medicinal MDMA containing capsule, you will be offered music, played through headphones, and are encouraged to wear a facemask. The two therapists are always present and available to support and encourage your healing process. As medicinal MDMA begins to take effect, you may experience a swell of feeling, energy, enhanced sensory awareness and openness.

Medicinal MDMA can also lead you to feel closer to your therapist and more trusting of them. There have been occasions where a patient has felt love and even sexual feelings towards the therapist(s) whilst under the influence of the medicine. While this can happen with any psychotherapy, patients may even feel this more strongly under the influence of medicinal MDMA. Your therapists have been very well trained in how to appropriately care for you without making judgements, and have signed up to a code of ethics that prohibits any sexual relations between patients and therapists, including after the therapy has ended.

We would like to offer you the option of your session being recorded. For some people this becomes a valuable record of what happened and can be used for further work on their issues. Others would prefer this were not done, so it will be your decision entirely.

As the dosed therapy session can extend over 6-8 hours, patients are provided with pre-planned meals, sleeping arrangements, a bathroom and dining space. The spaces are well-designed and aesthetically pleasing. The patient is made aware of all safety measures and equipment put in place to ensure their safety in the unlikely event of a medical complication.

**What are the risks and are there any side effects?**

Most patients rate adverse reactions as mild to moderate. You may experience some or no side effects. Possible side effects include: jaw tension, anxiety, dizziness, sleepiness, lack of appetite, nausea. Phase 2 trials have encountered no other unexpected medicine-related adverse events.   
  
To minimise risk the first session includes a low dose of medicinal MDMA to observe your individual reaction and to gauge future clinical requirements. The treating psychiatrist will discuss the dose of medicinal MDMA each session based on your individual reactions, preferences, and their professional judgement.

Patient name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ DOB: \_\_\_\_\_\_\_\_\_

I have been specifically advised of the following:

1. Trauma related memories may surface through the process of medicinal MDMA-assisted psychotherapy
2. Some clients have experienced reactions during the treatment sessions that neither

they, nor the administering clinician, have anticipated including but not limited to

strong emotional or physical sensations, disorientation, anxiety, nausea, muscle tension.

1. Subsequent to the treatment session, the processing of incidents and/or material

may continue, and dreams, memories, feelings, etc. may surface.

I have considered all the above and I have obtained whatever additional input and/or professional advice I deemed necessary or appropriate.

By my signature below I hereby consent to receiving medicinal MDMA as treatment for PTSD. My signature on this Information and Consent form is free from pressure or influence from any person or entity. I understand I may stop treatment at any time before or after a session and that more than one medicinal MDMA-assisted therapy session is usually necessary for successful treatment.

Patient Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_

1. https://www.beyondblue.org.au/the-facts/anxiety/types-of-anxiety/ptsd [↑](#endnote-ref-1)
2. https://maps.org/research-archive/mdma/MDMA-Assisted-Psychotherapy-Treatment-Manual-Version7-19Aug15-FINAL.pdf [↑](#endnote-ref-2)
3. Lee DJ, Schnitzlein CW, Wolf JP, Vythilingam M, Rasmusson AM, Hoge CW. Psychotherapy versus pharmacotherapy for posttraumatic stress disorder: systemic review and meta-analyses to determine first-line treatments. Depress Anxiety 2016; 33: 792–806. [↑](#endnote-ref-3)
4. Steenkamp MM, Litz BT, Hoge CW, Marmar CR. Psychotherapy for military-related PTSD: a review of randomized clinical trials. JAMA 2015; 314: 489–500. [↑](#endnote-ref-4)
5. Wagner, M. T., Mithoefer, M. C., Mithoefer, A. T., MacAulay, R. K., Jerome, L., Yazar-Klosinski, B., & Doblin, R. (2017). Therapeutic effect of increased openness: Investigating mechanism of action in MDMA-assisted psychotherapy. *Journal of Psychopharmacology*, *31*(8), 967-974. [↑](#endnote-ref-5)